



**Livestock and Seed Program
Audit, Review, and Compliance Branch
Quality System Audit Report**

AUDIT INFORMATION

Applicant Name:	Institute for Marketecology (IMO) Switzerland
Est. Number:	N/A
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Auditor(s):	Rick Skinner
Program:	USDA National Organic Program (NOP)
Audit Date(s):	May 30, 2008
Audit Identifier:	NP7051GGA EEA
Action Required:	No
Audit Type:	Corrective Action Audit
Audit Objective:	To verify that the corrective actions adequately address the outstanding non-compliances from the 2005 initial on-site and annual update audit and the non-compliances from the on-site Accreditation Renewal Audit.
Audit Criteria:	7 CFR Part 205 National Organic Program (NOP) Final Rule, dated December 21, 2000; updated December 12, 2007.
Audit Scope:	The company's submitted corrective actions.
Location(s) Audited:	Desk

Institute for Marketecology (IMO) Switzerland submitted corrective actions dated March 27, 2008.

FINDINGS

The corrective actions submitted by IMO adequately addressed the two outstanding non-compliances from the 2005 initial On-site and Annual Update Audit (NP5171OOA) and the thirteen non-compliances from the on-site Accreditation Renewal Audit conducted in Switzerland, Germany, Spain, and China.

NP5171OOA.NC3 – Minor – Adequately Addressed - NOP §205.404 states that if the certifying agent determines that the organic system plan and all procedures and activities of the applicant's operation are in compliance with the plan, the agent shall grant certification. *IMO 5.7 Contract NOP Finance states, "...furthermore it reserves the right to unannounced spot check controls and sampling for analysis, these costs are also covered by the mandatory. Also in I 2.1.1 G-e section 1.5 states, "All expenses necessary to conduct the inspections, evaluations, and certification will be charged to the mandatory. Requiring clients to pay for analysis is an additional requirement and cannot be used as a determination for*



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certification. **Corrective Action:** IMO has indicated that reference to costs of sampling analysis will not be included in the general invoice for inspection and certification but will be billed separately. This still indicates that clients will be billed for analysis of samples. **Corrective Action (January 22, 2007):** IMO has reviewed NOP §205.404 and concluded that there is nothing to indicate that the certifying body cannot charge for any sampling analysis that is conducted. However, according to NOP §205.670 b, "The administrator, applicable State organic program's governing State Official or the certifying agent may require preharvest or postharvest testing of any agricultural input used or agricultural product to be sold, labeled, or represented as "100 percent organic" "organic" or "made with organic (specified ingredients or food group(s))" when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance or has been produced using excluded methods. Such tests must be conducted by the applicable State organic program's governing State official or the certifying agent at the official's or certifying agent's own expense." **Corrective Action (April 7, 2007):** IMO submitted updated procedure, IMO I 5.1 CH-e IMO Standard Program for Certification to the NOP Rule PCB, from May 2006 Section 10.3 Costs and Services states, "the costs for analyses in NOP certifications are not charged to the client." **Onsite Audit Verification Activities (Feb. – Sept. 2007):** The IMO contract, the IMO working procedure V70, and additional references in the procedures require the cost of testing to be born by the producer or client. This is contrary to the requirement of this clause. **Corrective Action (March 27, 2008):** IMO stated that sample expenses will no longer be charged to the client. IMO Quality Manual documents have been corrected including IMO 4.2.1 & 4.2.5 contracts for operators, IMO I 2.1.1 the standard procedures, and IMO I 5.2 NOP procedures. The issues identified in the standard procedures (IMO I 2.1.1) are handed out to all clients prior to contractual agreements.

NP517100A.NC4 – Minor – Adequately Addressed – NOP §205.501(a)(6) states that a private or governmental entity accredited as a certifying agent under this subpart must: (6) Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services... *A review of the annual performance evaluations revealed that IMO was not conducting annual performance evaluations for personnel involved in certification located in offices other than Switzerland.* **Corrective Action:** IMO has developed a new form for annual performance evaluations. Performance evaluations for this year will be completed March 31, 2006. **Onsite Audit Verification Activities (Feb. – Sept. 2007):** Records did not support that annual performance evaluations are performed. The director keeps all performance evaluations separate from the personnel files; however, the files he maintains did not contain current performance evaluations for the personnel reviewed. A new system is currently being implemented with a new checklist for performance evaluations, but it had not been fully implemented prior to the date of the audit. IMO Germany has not performed any evaluations for any inspectors working from that office. **Corrective Action (March 27, 2008):** IMO has submitted a standard form for evaluation of certification personnel by their immediate superior. The staff's performance will be evaluated and documented annually. Performance evaluations for this year are to be finalized by September 30, 2008.

NP7051GGA.NC1 – Adequately Addressed - NOP §205.303(b) states, "Agricultural products in packages described in §205.301(a) and (b) must: (2) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, "Certified organic by * * *," or similar phrase, identify the name of the certifying agent that certified the handler of the finished



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product....” *Finished product packaged as “Aunt Patty’s Organic Sunflower Kernels” packed by Dalian New-Ox in Dalian, China stated “Certified Organic by QAI”. The applicant stated this was because the distributor receiving the product (Glorybee Foods, Eugene, OR) was certified by QAI and they did not want to have to repackage the product. The inspector identified a non-compliance for the name of the company (Dalian New-Ox) not being on the bags but did not mention the certification agent. **Corrective Action:** IMO has informed the inspector the mistake of not identifying the certifying agent and of IMO only being able to approve labels where IMO is mentioned as the certifier. IMO will develop a new training module on NOP labeling by which all NOP inspectors will be trained. The training module will be based on the requirements of the Standard, the explanations on the NOP Homepage and actual label examples. The training documentation is planned to be completed by June 30, 2008.*

NP7051GGA.NC2 – Adequately Addressed - NOP §205.307(b) states, “Nonretail containers used to ship or store raw or processed agricultural product labeled as containing organic ingredients must display the production lot number of the product if applicable.” *Bags of soybean meal kept in the oil processing warehouse in Dalian, China did not contain any form of identification on the bags. There were no records to verify that the product was in fact organic and it was transferred from one company to the next. The company stated this was because they considered it an internal transfer. However, they are operating as two separate certified operations. **Corrective Action:** The inspector identified this area as a finding during the inspection and pointed out this fact to the operator. IMO submitted a scanned copy with the translation of the condition imposed by the inspector during the witness audit.*

NP7051GGA.NC3 – Adequately Addressed - NOP §205.401(d) states, “The application must include the following information: Other information necessary to determine compliance with the Act and the regulations in this part.” Additionally, IMO I – 2.1.01 G-e Standard Procedures for certification Section 7.2 and IMO’s Work Instruction Number 53 for NOP Labeling Requirements version July 2007 require the approval by IMO for all export and final consumer labels prior to printing. *Records show that most labels are currently being evaluated and approved by the contract or staff inspectors during the onsite inspections. This is contrary to the company procedure, and NOP standards, which require the ACA to review application materials (§205.404(a), §205.405(a) and §205.406(c)) and inspectors to verify information (§205.403(c)). **Corrective Action:** IMO has mentioned that final retail labels are currently being approved by IMO Switzerland but have not always approved the export labels. IMO has mentioned that operators will not be certified until they send in sample labels for export and retail products (as described in the Work Instruction 53). In addition, IMO will develop a new training module on NOP labeling by which all NOP inspectors will be trained. The training module will be based on the requirements of the Standard, the explanations on the NOP Homepage and actual label examples. The training documentation is planned to be completed by June 30, 2008.*

NP7051GGA.NC4 – Adequately Addressed - NOP §205.402(a) requires the certifying agent to accept applications for certification and must: (1) review the application for completeness; (2) determine if the applicant does or has the ability to comply with the regulation; (3) verify if an applicant has previously applied to another certifying agent; and (4) schedule the on-site inspection. (b) requires the certifying agent within a reasonable time to: (1) review application materials received and communicate its findings to the applicant; and (2) provide the applicant with a copy of the on-site inspection report, as approved by the certifying agent. *The duties detailed in this section of the regulation are performed at the regional offices. The completion of these duties could not be verified in the materials maintained at the office in*



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Weinfelden, as the records for the review process are maintained in the regional offices. The IMO office in Weinfelden, Switzerland receives the completed inspection report, the OSP, and the recommendation from the regional office. The timeframe for the process could not be verified with the information available in the client files at the Weinfelden office. **Corrective Action:** IMO has issued a new work instruction that explains all details to be kept by the Regional Offices in summarized way for new clients so that the information can be sent to Switzerland. The Work Instruction and annex is to be completed for all new NOP clients by all IMO Offices performing NOP inspections.

NP7051GGA.NC5 – Adequately Addressed - NOP §205.403(b) (2) states, “All on-site inspections must be conducted when an authorized representative of the operation who is knowledgeable about the operation is present and at a time when land, facilities, and activities... can be observed....” *During the China witness inspection, the processor was not in production and the inspector stated that the inspection would count towards certification. An inquiry on the 2006 inspection verified that the operation was not in production at the time of that inspection either. During the witness inspection, the inspector which also conducted the previous inspection stated that the company was not in production at the time of the 2006 inspection.* **Corrective Action:** IMO stated that they had limitations for scheduling this inspection due to requirements by USDA regarding type of operation, date, and location to make the witness audits in China. Therefore, it was difficult to schedule these inspections at the best possible time. However, IMO will perform a spot check inspection when the operation is in activity and has offered to inform the NOP of the results if necessary.

NP7051GGA.NC6 – Adequately Addressed - NOP §205.403 (c)(1) states, “The on-site inspection of an operation must verify: the operation’s compliance or capability to comply with the Act and regulations in this part.” *An audit trail on the incoming product and production record for a lot of soybeans was conducted by the inspector during the witness audit in Dalian, China. However, the calculations conducted did not account for the oil production from the soybeans. The inspectors stated the IMO checklist does not require this and thus was not considered in the calculations. The difference in the unaccounted product was 56.8 metric tons. During the tour of one processor, the inspectors reviewed two pallets of organic product and did not review or observe the other two pallets. Additionally, none of the six to eight pallets of conventional product were reviewed. Pallets were covered with tarps and could not be observed unless the tarps were lifted. An audit trial conducted on product did not account for all product used during production.* **Corrective Action:** IMO stated that the inspection report did include the product flow of raw products (soybeans) compared to the quantity of soybean meal and soybean oil produced. The sales of the organic soybean meal were verified but not the soybean oil since it was sold as conventional product. IMO also stated that the inspector identified this area as a finding (the 56.8 metric tons of unaccounted product) during the inspection and pointed out this fact to the operator. IMO submitted a scanned copy with the translation of the condition imposed by the inspector during the witness audit.

NP7051GGA.NC7 - Adequately Addressed - NOP §205.501(a)(5) states “Ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned.” *The inspector had limited experience with processors in general and of organic processing and handling techniques. The inspector indicated the client needed to maintain a “buyers list”. When asked to which standard the requirement to maintain a buyers list came from he was*



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*not sure. When questioned on whether the requirement was a USDA National Organic Standard requirement he did not know. **Corrective Action:** IMO has acknowledged that this was a requirement of the EEC 2092/91 and not specifically by the NOP. However, IMO has considered the importance of having the information of which the certified operation conducts business with so that an audit trail can be conducted up to the point of the sale. IMO has mentioned that the inspector will be informed and that this information will be included in future trainings.*

NP7051GGA.NC8 – Adequately Addressed - NOP §205.403(e)(1) states, “At the time of the inspection, the inspector shall provide the operation’s authorized representative with a receipt for any samples taken by the inspector.” *A sample was collected from two processors during the witness inspections in Dalian, China but no receipt was provided to the operations. The inspectors stated they only provide a receipt if the operation requests a copy. The second operation was asked if they would like a receipt but they stated they did not. **Corrective Action:** IMO will instruct all inspectors on this requirement and include in future training plans. IMO also mentioned that providing the receipt for samples taken is listed in IMO I 4.6.1 G-e Sample Withdrawal Procedure. IMO has stated that they will provide these two operations with copies of sampling sheets as the receipts.*

NP7051GGA.NC9 – Adequately Addressed - NOP §205.406(a)(1) states, “To continue certification, a certified operation must annually pay the certification fees and submit the following information, as applicable, to the certifying agent: An updated organic production or handling plan....” *IMO does not require the submission of an updated organic system plan. A review of 13 files identified only one having an updated organic system plan prior to arrangements for inspection. The inspector is required to update the organic system plan at the time of inspection. **Corrective Action:** IMO requires an updated organic system plan to be available before inspection as noted in the Standard Procedures. IMO has mentioned that they will enforce this requirement in the future by sanctioning clients that do not send in updated profiles before inspections. This information was also communicated to the IMO Offices.*

NP7051GGA.NC10 - Adequately Addressed - NOP §205.501(18) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Provide the inspector, prior to each on-site inspection, with previous on-site inspection reports and notify the inspector of its decision regarding certification of the production or handling operation site inspected by the inspector and of any requirements for the correction of minor non-compliances.” *IMO does not currently have a procedure for conveying the results of certification decisions back to the inspector who performed the inspection. **Corrective Action:** IMO has adapted IMO I 5.2 Internal Procedures NOP, and added the part that certification results need to be communicated to the inspectors.*

NP7051GGA.NC11 – Adequately Addressed - NOP §205.501(a)(4) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Use a sufficient number of adequately trained personnel, including inspectors....” *Client file reviews and on-site witness inspections revealed that the label approval is being performed by the inspector during the inspection. Training documents revealed that the inspectors have not received specific training in label requirements for NOP. **Corrective Action:** IMO will now prepare specific label training for inspectors and evaluators with regard to NOP requirements and send out until July 30, 2008.*

NP7051GGA.NC12 – Adequately Addressed - NOP §205.501(a)(11)(v) requires all persons who



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review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent to complete an annual conflict of interest disclosure report. *A review of personnel files disclosed that: Five of eight Certification Officers conflict of interest disclosure reports were at least fourteen (14) months since the last declaration, and six of twelve inspectors conflict of interest declarations were at least thirty (30) days past due.* **Corrective Action:** IMO procedures Work Instruction 34 requires conflict of interest disclosures to be submitted for each calendar year. IMO has included point 6 Documentation, third bullet point which refers to the annual verification of the personnel files, especially stressing the declaration of interests. IMO also has shown the requirement as being fulfilled.

NP7051GGA.NC13 – Adequately Addressed - NOP §205.501(a)(16) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Charge applicants for certification and certified production and handling operations only those fees and charges for certification activities that it has filed with the Administrator.” *IMO has established a new fee structure for 2007, which clients have been charged for their 2007 certification services. The new fee structure has not been filed with the Administrator. Fee structure are different for each country in which IMO does business, and the fee structure for partner companies is not published at all. The fee structure is a flat fee for certification.* **Corrective Action:** Fees tables are renewed annually, monitored by the QS Department, and once approved, are available for all IMO personnel on the Remote Server. The updates are submitted to the NOP.